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(71) Applicant: BIOCOMPATIBLES LIMITED [GB/GB]; Chapman House, Weydon Lane, Farnham GU9 8QL (GB).

(72) Inventor: HEALY, Denis, Dominic; Woodview, Stradbally East, Kilcolgan, Co. Galway (IE).

(74) Agents: WALLACE, Sheila, Jane et al.; Lloyd Wise, Commonwealth House, 1-19 New Oxford Street, London WC1A 1LW (GB).

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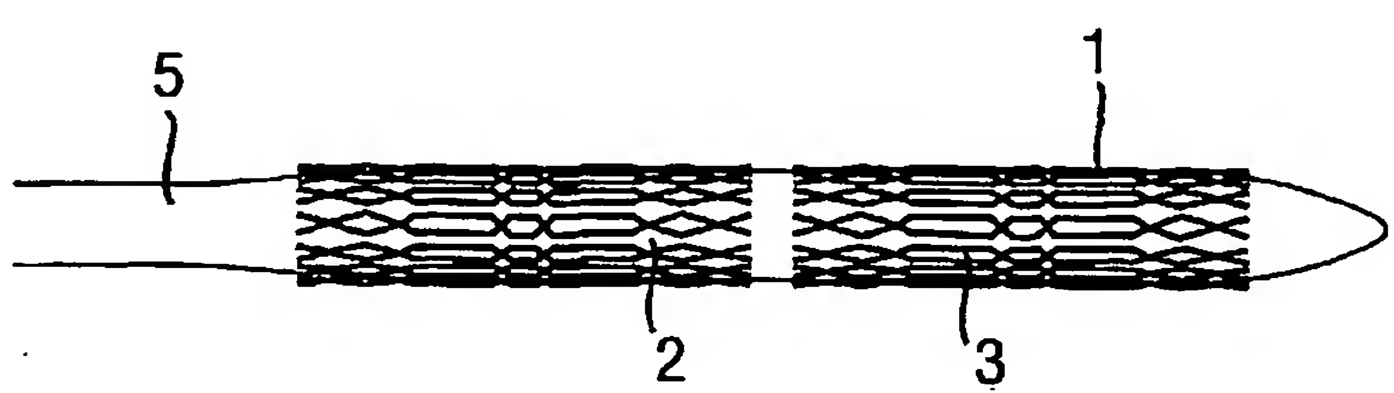
(54) Title: METHOD FOR MANUFACTURING A STENT



(57) Abstract: A method of manufacturing a stent formed from a metal or metal alloy includes the steps of applying a powder of a material having a higher radiopacity than that of the material from which the stent is formed to a region of the surface of the stent, and applying laser light to the surface having the radiopaque powder placed thereon so that the powder is incorporated into the surface of the stent. The method may also include forming said stent from stainless steel. In addition, the powder may be selected from the group including gold, platinum, tantalum, niobium, titanium, or tungsten or a combination thereof and the laser light may be generated by a YAG laser, a CO_2 laser, a Diode laser or a Femto laser. Alternatively, a stent may be provided formed from a metal or metal alloy with the stent having the powder impregnated in the surface thereof.

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METHOD FOR MANUFACTURING A STENT

FIELD OF THE INVENTION

The present invention relates generally to a manufacturing process for stents and stents formed by the manufacturing process, and in particular to methods and stents formed therefrom having increased radiopacity.

BACKGROUND OF THE INVENTION

A stent is a medical device, usually a hollow tubular structure, which is inserted into a body lumen to provide support thereto. Stents are well known in the art and there are many different types of stents available. Some are configured to be expanded after being located at a desired position in the lumen by an expansive force provided by an inflatable balloon. Others are delivered under compression so that, upon delivery they expand to provide the necessary supporting force. Others are made from heat-sensitive materials that expand at body temperature to provide the necessary supportive force.

In recent times there has been a desire to form such stents from smaller and smaller quantities of material to provide greater flexibility, i.e., so that they are more flexible prior to delivery. There has also been a desire to produce stents for smaller lumens. Whilst such stents are often made from materials which are radiopaque, this desire for reduced amounts of material in the stents has led to the stents becoming less radiopaque and, as such, difficult to see under X-ray either during or after deployment.

Attempts have been made to overcome this lack of visibility problem by attaching to the stent pieces of radiopaque material, such as gold. Doing this introduces problems, however, in that it increases the overall bulk of the stent, making it difficult to produce for insertion into small lumens, and reducing its flexibility. It is also difficult to handle the very small pieces of radiopaque material, making manufacture difficult and unreliable. There is also the risk that the attached radiopaque component may detach itself in the body, potentially causing a serious health risk. An alternative approach has been to coat the stent with radiopaque material, again such as gold, in order to increase radiopacity. However, this approach is difficult because of the complexity of the coating processes and because a failure to coat correctly can lead to problems, such as galvanic corrosion.

SUMMARY OF THE INVENTION

The present invention seeks to provide a method, and a stent produced therefrom, which increases the radiopacity of the stent without causing some of the problems associated with previous attempts at increasing radiopacity.

According to the present invention there is provided a method of manufacturing a stent formed from a metal or metal alloy, with the method including the steps of applying a powder of a material having a higher radiopacity than that of the material from which the stent is formed to a region of the surface of the stent, and applying laser light to the surface having the radiopaque powder placed thereon such that the surface melts to incorporate the powder.

In addition, the preferred embodiment of the method may include the step of forming the stent from stainless steel. Also, the powder may be formed from gold, platinum, tantalum, niobium, titanium or tungsten or a combination thereof.

The powder may be applied at the same time as applying the laser light. The powder may also be applied by cold gas dynamic spraying.

The laser light may be generated by a YAG laser, a CO_2 laser, a Diode laser or Femto laser. The method may also include the step of cutting holes in the stent using the same laser either before or after fixing the powder to the surface of the stent.

The laser light may be applied to the powder at least twice in order to smooth the surface profile of the end product.

The present invention also may be used to manufacture a stent formed from a metal or metal alloy, with the stent having a powder impregnated in the surface thereof and the power being formed from a material having a radiopacity greater than that of the metal or metal alloy.

The stent of the present invention, manufactured by applying a powder of a material having a higher radiopacity than that of the material from which the stent is formed to a region of the surface of the stent and applying laser light to the surface having the radiopaque powder placed thereon so that the powder is incorporated into the surface of the stent, includes a body portion having an outer surface with a powder having a higher radiopacity than that of the material from which the stent is formed incorporated into at least a portion of the surface of the stent. In the preferred embodiment of the stent, the powder is selected from the group including gold, platinum, tantalum, niobium, titanium or tungsten or a combination thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

Other advantages of the present invention will be readily appreciated and apparent to those skilled in the art as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, in which:

Figure 1 is a side view of a known stent;

Figure 2 is a side view of a stent manufactured in accordance with the present invention;

Figures 3A and 3B are schematic diagrams of the steps of the method of the present invention; and

Figures 4A-4C are a series of images of the surface of stents produced in accordance with the method of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to figure 1, a known stent 1 is shown. The stent 1 has a body portion formed from a hollow tube of metal or metal alloy, usually stainless steel, as is well known in the art with cuts or openings in the surface of the stent 1 in a series of holes 2 which define struts 3. The stent shown is a balloon-expandable stent 1 and the struts 3 are shaped so that, when a balloon 5 is inserted into the stent 1 and expanded, the stent 1 expands to form a rigid structure that can support a body lumen. It will be appreciated that, whilst the method of the present invention is described with reference to such a balloon-expandable stent 1, the teaching herein could equally be applied to other types of stent, such as those which are constructed to be self-expanding either due to the forces formed within the stent or through being formed from a heat-sensitive material such as nitinol.

Figure 2 shows a stent 1 according to the present invention in which components that correspond to those in the known stent 1 of figure 1 are numbered identically. As can be seen from this figure, the stent 1 according to the invention has regions 4 of higher radiopacity 4 bonded on struts 3 at either end of the structure of the stent 1. These regions 4 of higher radiopacity enhance the visibility of the stent 1 under x-ray imaging so that, either during deployment or after deployment, a surgeon can more easily view the location of the stent 1.

Figure 3A illustrates a preferred embodiment of the method of the present invention at various stages in the process of manufacturing the stent 1 of Figure 2. Initially, a hollow tube of metal, such as stainless steel, is provided with holes 2 etched or cut therein with a laser 6 which may be a YAG laser or, more cost effectively, a CO_2 laser. Powdered radiopaque material is then applied either manually or automatically to at least a portion of the struts 3 at either end of the

stent 1. Laser light, either from a separate laser light source or the same laser light source 6 that carried out the etching, is then applied so as to either melt the powder, or the surface of the struts 3, or both, when the light is applied in order to impregnate the surface of the stent 1 with the powder to form a radiopaque region 4. The process is repeated in order to provide sufficient number of radiopaque regions 4 to ensure good visibility of the stent 1 in use. The laser 6 may be applied a second time in order to smooth the overall surface.

Figure 3B illustrated another embodiment of the method of the present invention. In this embodiment, the powder is applied simultaneously with the laser light application. This may involve use of a laser light source 6 with a surrounding powder dispensing nozzle 7 or a separate nozzle 7, both of which are shown in the figure. In this case, the speed of the particles of the powder will preferably be in the range of 0.1 to 20m per second, providing flow rate for the powder particles which will be in the region of 1 to 1000 μg per second. Preferably, the powder is fed with an inert gas such as argon, helium or nitrogen. Again, the laser may be applied a second time, during which powder is not fed to the surface of the stent.

In both embodiments, the method may employ one of a number of types of lasers, and in general it would be expected that the power of the laser would be no more than 50 Watts.

The method of the invention may be employed using a YAG welding laser with a Nb-Ti alloy powder, and Figure 4A shows a radiopaque region formed by such an approach. A 250 am wide line of radiopaque region is formed which rises about 15 to 20 μm from of the surface of the stent 1. The laser light was applied as spots which overlapped, and a higher repetition of the spots can increase the smoothness of the applied radiopaque region as can be seen from Figure 4B. Figure 4C shows how the radiopaque region of Figure 4B can be further smoothed by passing the laser light over the region for a second time.

The description given above provides example of various embodiments for implementing the method of the present invention and the stent produced therefrom. Variations and modifications may become apparent to those skilled in the art that do not necessarily depart from the basis of this invention. The scope of legal protection given to this invention can only be determined by studying the following claims.

CLAIMS

What is claimed is:

1. A method of manufacturing a stent formed from a metal or metal alloy comprising the steps of:

applying a powder of a material having a higher radiopacity than that of the material from which the stent is formed to a region of the surface of the stent; and

applying laser light to the surface having the radiopaque powder placed thereon so that the powder is incorporated into the surface of the stent.

2. The method of manufacturing a stent set forth in Claim 1, further comprising the step of forming said stent from stainless steel.

3. The method of manufacturing a stent set forth in Claim 1, wherein said powder is selected from the group including gold, platinum, tantalum, niobium, titanium or tungsten or a combination thereof.

4. The method of manufacturing a stent set forth in Claim 1, wherein the steps of applying the powder and applying the laser light may be undertaken simultaneously.

5. The method of manufacturing a stent set forth in Claim 1, wherein the powder may be applied by cold gas dynamic spraying.

6. The method of manufacturing a stent set forth in Claim 1, wherein the laser light may be generated by a YAG laser, a CO_2 laser, a Diode laser or a Femto laser.

7. The method of manufacturing a stent set forth in Claim 1, further comprising the step of cutting holes in the stent using the same laser either before or after fixing the powder to the surface of the stent.

8. The method of manufacturing a stent set forth in Claim 1, wherein the laser light may be applied to the powder at least twice in order to smooth the surface profile of the stent.

9. A method of manufacturing a stent formed from a metal or metal alloy comprising the steps of:

providing a stent formed from a metal or metal alloy with the stent having a powder impregnated in the surface thereof and the powder being formed from a material having a radiopacity greater than that of the metal or metal alloy; and

applying laser light to the surface having the radiopaque powder placed thereon so that the surface melts to incorporate the powder.

10. The method of manufacturing a stent set forth in Claim 1, wherein said powder is selected from the group including gold, platinum, tantalum, niobium, titanium or tungsten or a combination thereof.

11. A stent manufactured by applying a powder of a material having a higher radiopacity than that of the material from which the stent is formed to a region of the surface of the stent and applying laser light to the surface having the radiopaque powder placed thereon so that the powder is incorporated into the surface of the stent, the stent comprising:

a body portion having an outer surface with a powder having a higher radiopacity than that of the material from which the stent is formed incorporated into at least a portion of the surface of the stent.

12. The stent set forth in Claim 11, wherein said powder is selected from the group including gold, platinum, tantalum, niobium, titanium or tungsten or a combination thereof.

FIG. 1

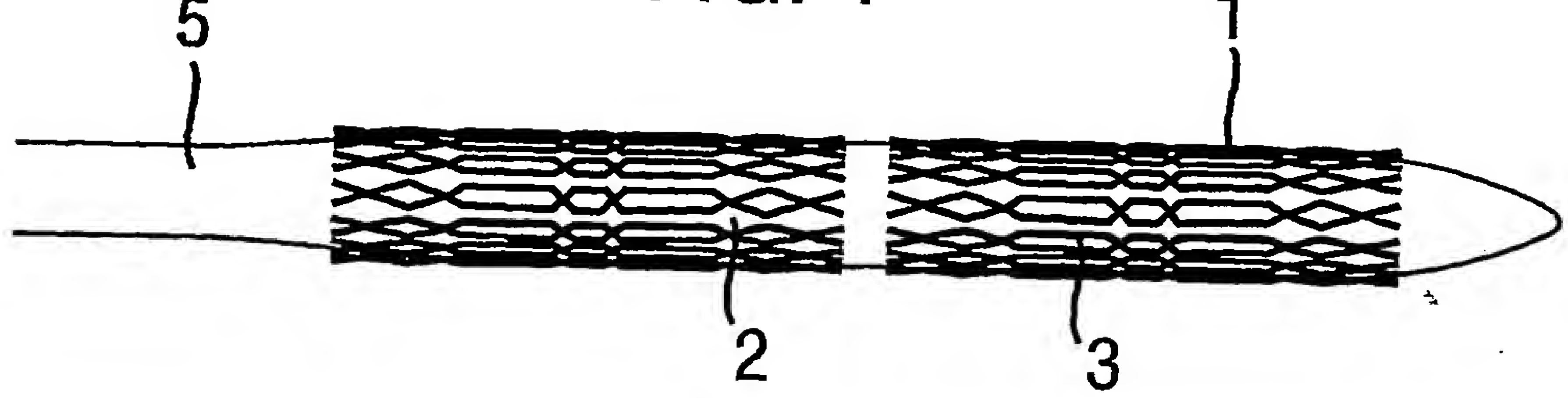
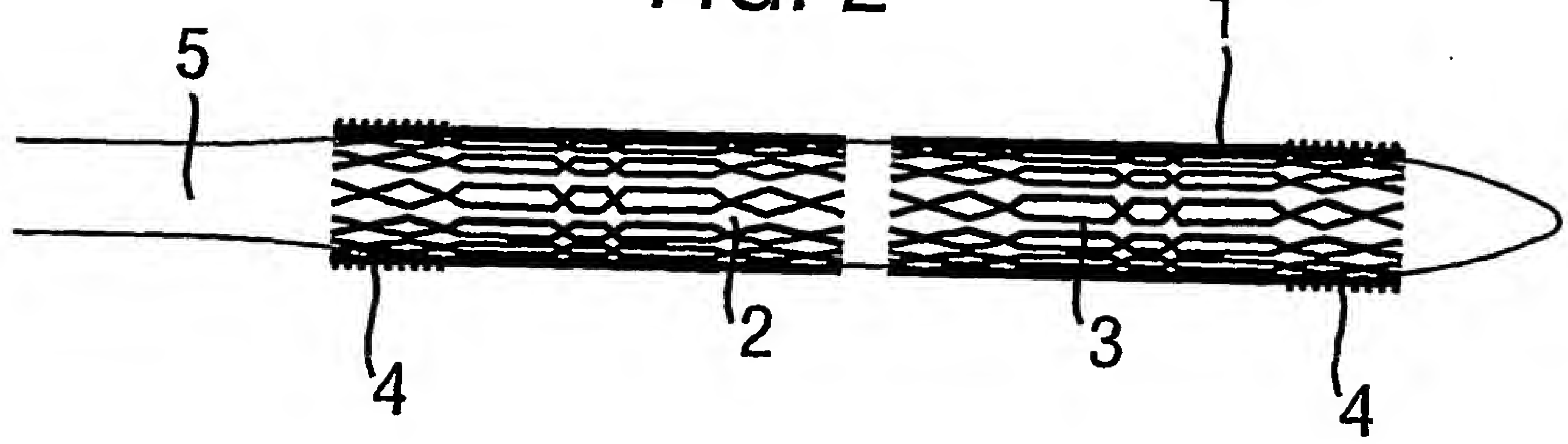


FIG. 2



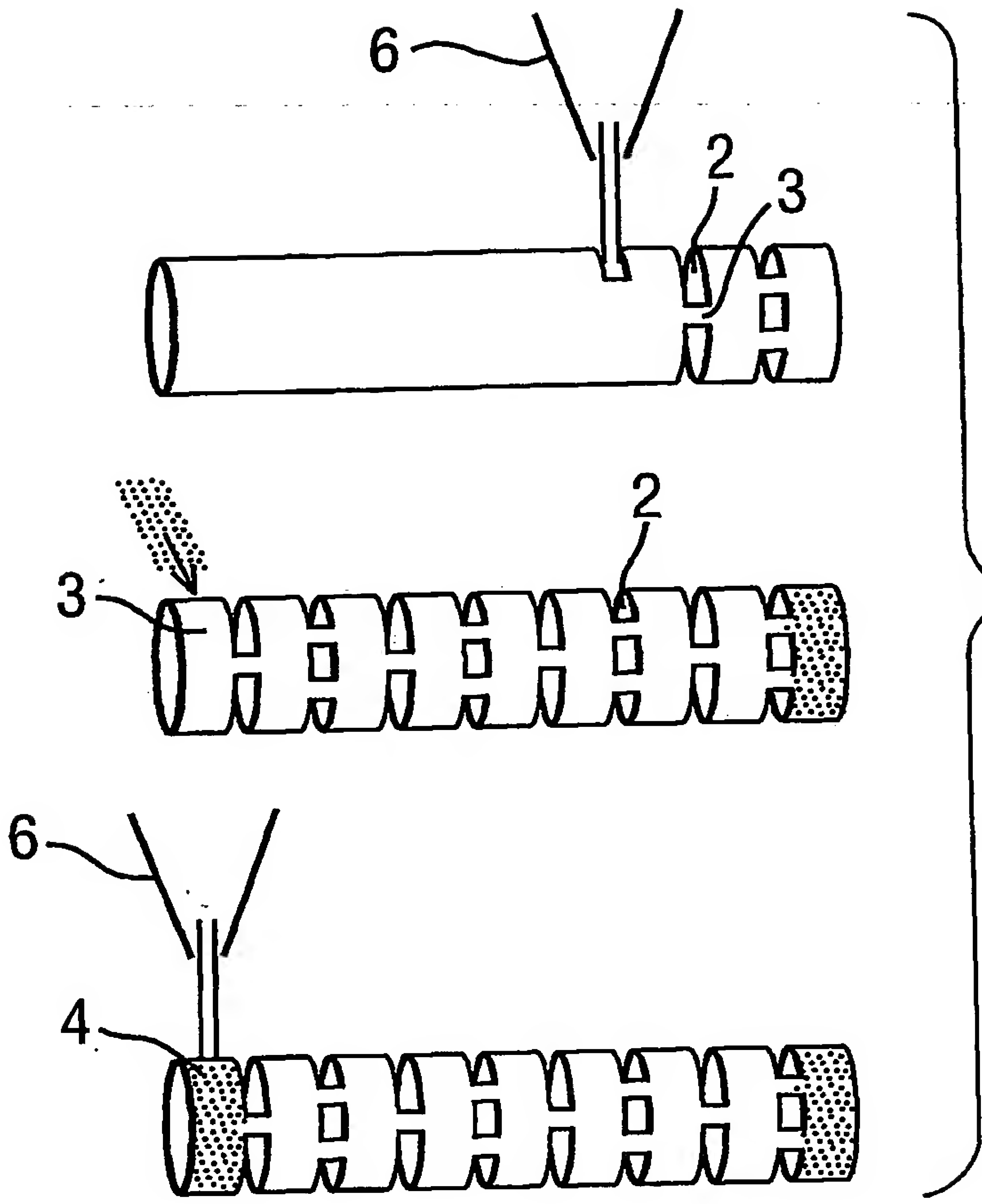


FIG. 3A

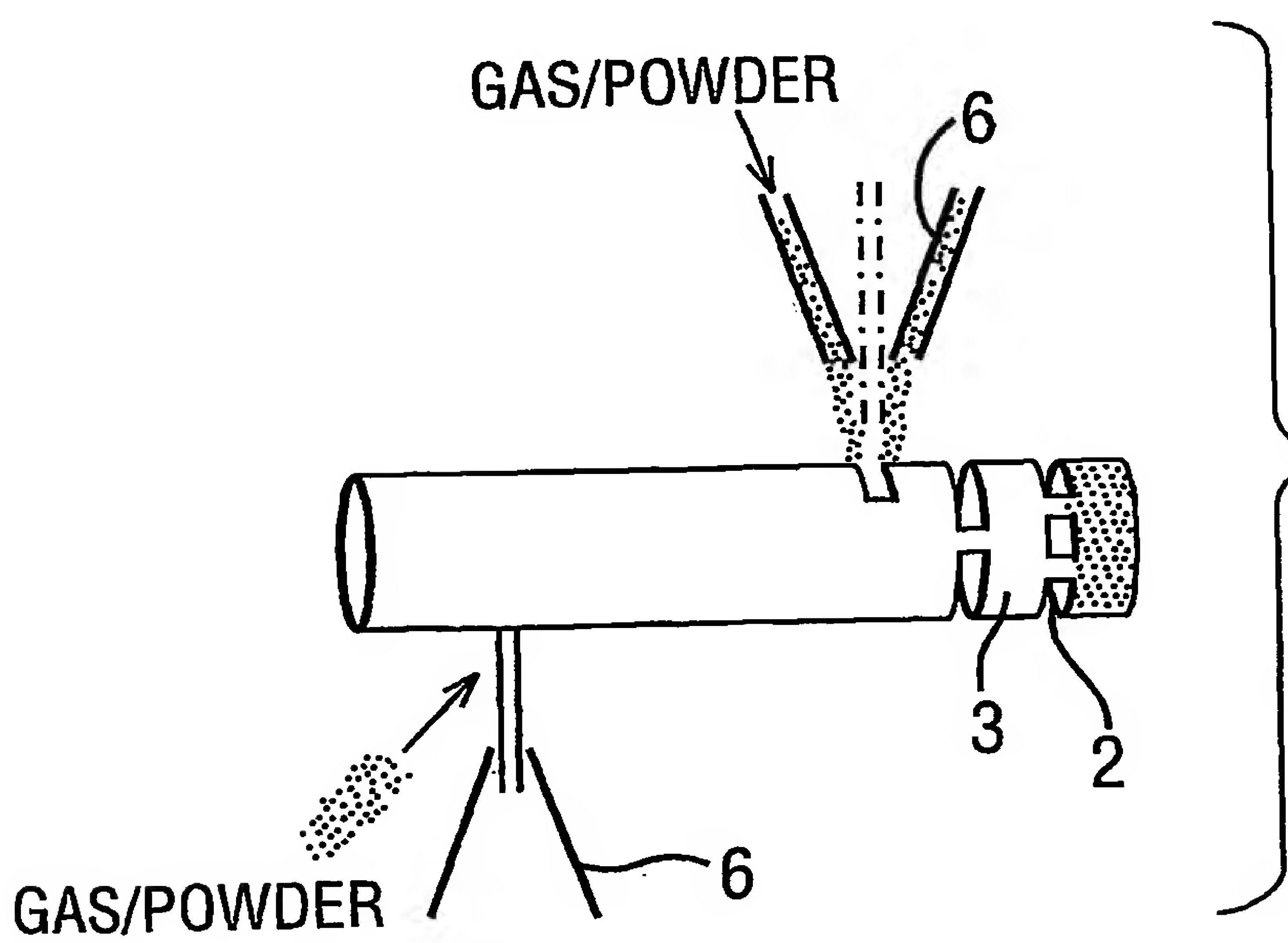


FIG. 3B

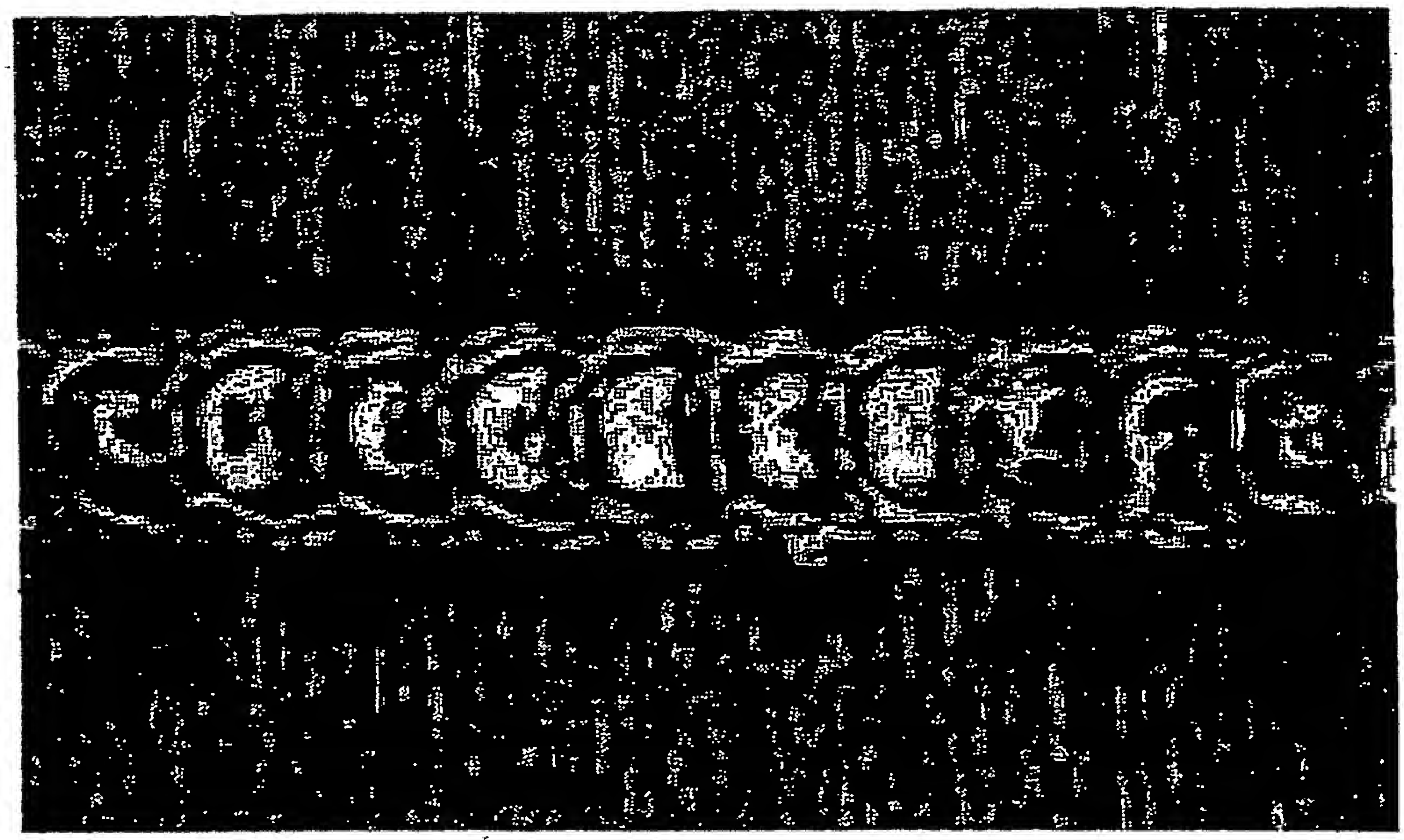


FIG. 4A

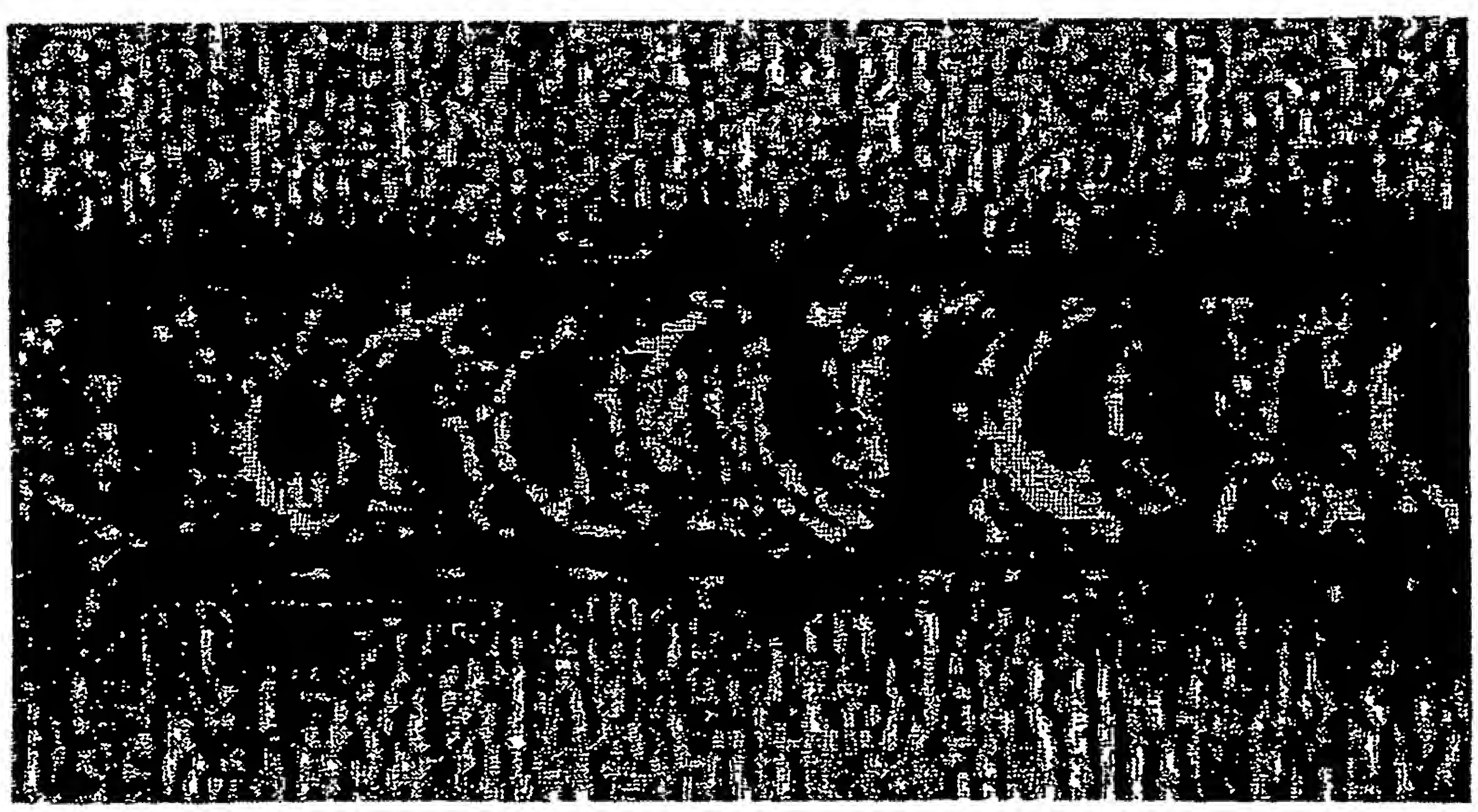


FIG. 4B

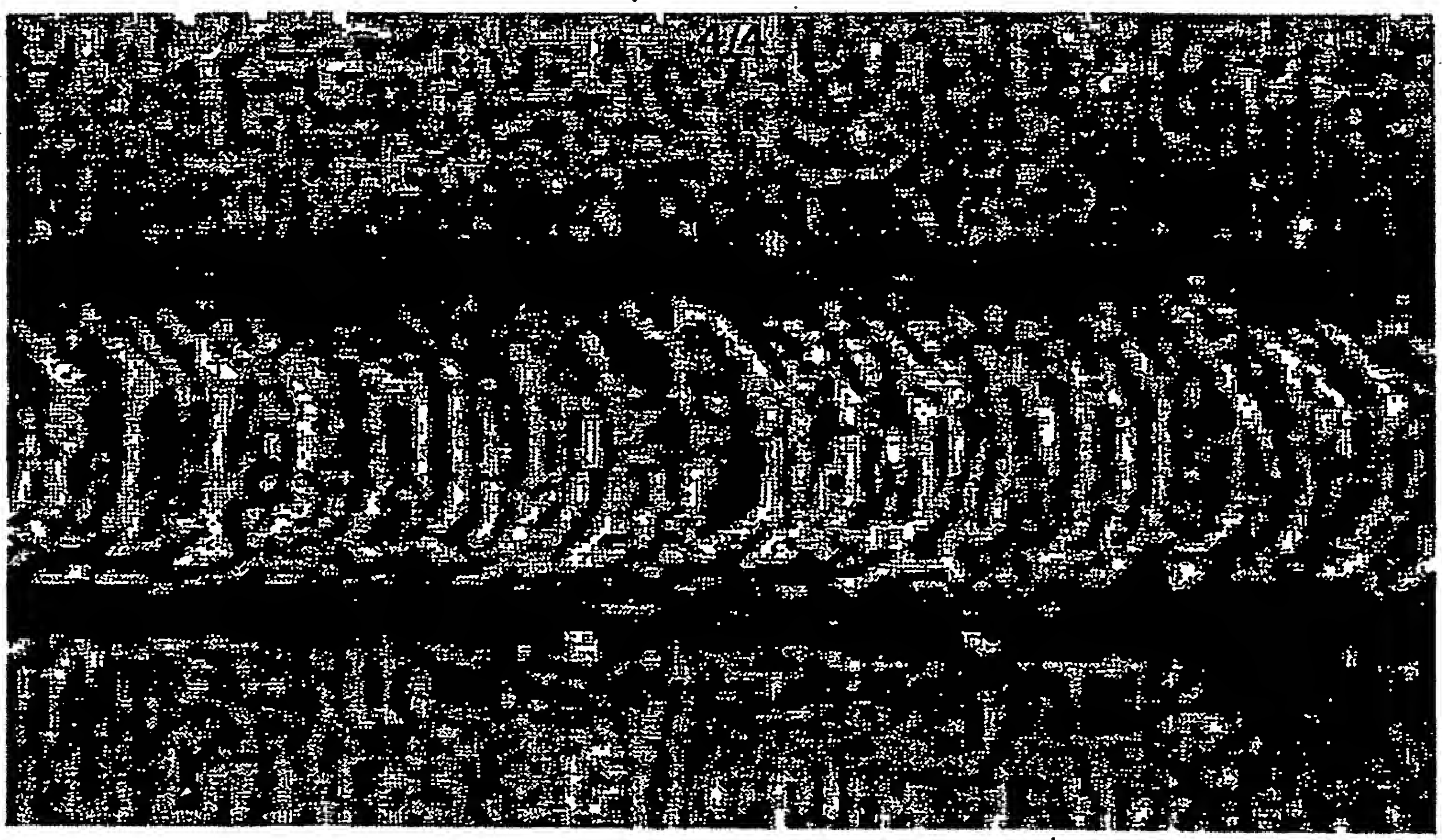


FIG. 4C